REMARKS

Claims 1-59 are pending in this application. Claims 1-31 as amended without prejudice and new claims 32-59 are presented for the Examiner's review and consideration. Claim 31 has been amended to depend from claim 1. No new matter has been added, as the amendments and new claims are supported by the specification as originally filed.

In the Office Action, Claims 1, 4, 5, 10 and 31 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner stated:

> "The term "varnish-like" in claims 1, 4, 5, 10 and 31 is indefinite because it is unclear as to how the term "varnish" would be distinguished or distinct from the term "varnish-like". The terms appear to be equivalent. Clarification is requested."
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> (Office Action mailed 6/30/2003, page 2, lines 15-17).

As described in the specification, the term *varnish-like* means that the coating bonds with the surface of the base material with enough adhesive strength such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating, or at least, not to such an extent as to compromise its physical effect. (Specification, 4:28-31). Applicants respectfully submit that further clarification is not required as the definition being relied upon to claim the invention is clear. (See, MPEP 2173.05(a)). Accordingly, applicants submit that the rejection of claims 1, 4, 5, 10 and 31 under 35 U.S.C. 112, second paragraph has been overcome and should be withdrawn.

Claims 1-5, 7-12, 16, 17, 21-23 and 29-31 were rejected under 35 U.S.C. §102(b) as being anticipated by Arm et al. (WO 93/20859) ("Arm"). The Examiner stated:

> "Arm at al. disclose implants and prosthetic devices having an outer surface coated with biodegradable polymeric films, which comprise polylactic acid/polyglycolic acid copolymers, therapeutically effective amounts of growth factors, active agents and carriers, wherein the polymeric films have a preferred thicknesses of less than about 50 microns. The films may be affixed to the outer surface of the implant or prosthetic device, which include a screw, pin, plate, rod or artificial joint component. The films and rods are therapeutically useful for promoting tissue growth and repair, particularly for enhancing repair of bone fractures (see page 3 line 32 through page 7, line 10) and abstract and claims."
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> (Office Action mailed 6/30/2003, p. 3:9-17).

Claim 1 has been amended without prejudice to recite: "Implant for compensating for pathological changes in the spinal column or locomotor system comprising a varnish-like biodegradable polymer coating of a thickness of 100 μm or less, wherein the varnish-like

biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo." Arm does not disclose, teach, or suggest an implant having a "varnish-like" coating as recited by claim 1. Rather, Arm discloses biodegradable films loaded with growth factors. (Arm, 1:8-9). The films disclosed by Arm are prepared and stored refrigerated (e.g., 4° C) until use. (Arm, 13:6-8). In contrast to the varnish-like coating recited by claim 1, Arm discloses "wrapping" such biodegradable films on surgical screws, rods, pins, plates and the like. (*Id.*, 13:11-13). Arm, moreover, is understood to be silent as to providing a varnish-like coating on an orthopedic implant as required by claim 1.[1] Thus, applicant's respectfully submit that Arm does not disclose, teach, or suggest each and every limitation of claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) has been over come and should be withdrawn.

With respect to claims 2-5, 7-12, 16, 17, 21-23, 29-31, which depend from independent claim 1, applicants submit that because these claims define more particular aspects of applicants' invention in addition to the features and elements of independent claim 1, these claims are also patentably distinct from Arm for the same reasons as claim 1, as well as the additional features of claims 2-5, 7-12, 16, 17, 21-23 and 29-31.

For example, claims 21 and 31 require preparing a dispersion of the biodegradable polymer in an organic solvent, applying the dispersion on a surface of the implant to be coated, and allowing the solvent to evaporate. As previously described, Arm does not disclose, teach, or suggest applying the dispersion on a surface of the implant to be coated, and allowing the solvent to evaporate, as required by claims 21 and 31. Moreover, claim 23 further requires that the evaporation of the solvent occurs in a gaseous atmosphere substantially saturated with solvent vapor. Arm, by contrast, is understood to teach allowing the solvent to evaporate completely in a slow air flow hood. (Arm, 15:8-9). Thus, claims 21-23 and 29-31 are also believed to be patentably distinct from Arm for the additional features of claims 21-23 and 29-31.

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[1] As previously described, the term varnish-like requires that the coating bonds with the surface of the base material with enough adhesive strength such that, when the implant is implanted, mechanical friction will not abrade or otherwise damage the coating, or at least, not to such an extent as to compromise its physical effect. For example, as described in the specification, it is understood that one may properly drive a nail, provided with the varnish-like coating, into the bone without any significant abrasion of the varnish-like coating. (Specification, 4:32-33). The specification notes, for example, that a nail wrapped with a foil cannot be inserted in the medulla in a way that the foil which only loosely envelops the nail, actually reaches the point of its intended healing action. (*Id.*, 1:29-32). Thus, Arm, by contrast, is understood not to disclose, teach or suggest a varnish-like coating or a biodegradable film having the properties of a varnish-like coating.

Claims 1, 2, 4, 5, 8-10 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Eitenmuller et al. (US Pat. No. 4,610,692) ("Eitenmuller"). The Examiner stated:

> "Eitenmuller disclose an implant for filling bone cavities and fixing bone fragments in a living body comprising at least one coating of predetermined thickness, about 4 microns to about 30 microns, of a biodegradable substance selected from at least one of polymethacrylate, polylactide, polydextran and cellulose-based substances, wherein the implant also comprises at least one therapeutically active ingredient (see reference column 3, line 10 through col. 4, line 36); (col. 6, lines 14-25); (col. 7, lines 23-44); and claims."
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> (Office Action mailed 6/30/2003, pp. 3:20-24 to 4:3-4).

Claim 1 has been amended without prejudice to recite, *inter alia*, implant for compensating for pathological changes in the spinal column, wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo. Eitenmuller does not disclose, teach, or suggest an implant "wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo." Rather, Eitenmuller discloses a sintered tricalcium phosphate implant for filling bone cavities and for fixing bone fragments in a living body, comprising a discretely shaped, porous body of tricalcium phosphate, at least one therapeutically-active ingredient impregnated into said porous body and distributed among the pores therein, and at least one coating of predetermined thickness of a biodegradable substance on at least a portion of the porous body impregnated with therapeutically-active ingredient, whereby the time of absorption of said therapeutically-active ingredient is controlled by the thickness of said biodegradable substance. (Eitenmuller, 3:33-46). Contrary to the limitations of claim 1, the coated implant of Eitenmuller does not have substantially constant physiochemical state under physiological conditions in vivo. Rather, the implant of Eitenmuller is designed to release at least one therapeutically-active ingedient which is distributed among the pores within the implant. (*Id.*, 5:68-6:1). Thus, applicant's respectfully submit that Eitenmuller does not disclose, teach, or suggest each and every limitation of claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) has been over come and should be withdrawn.

With respect to claims 2, 4, 5, 8-10 and 20, which depend from independent claim 1, applicants submit that because these claims define more particular aspects of applicants' invention in addition to the features and elements of independent claim 1, these

claims are also patentably distinct from Eitenmuller for the same reasons as claim 1, as well as the additional features of claims 2, 4, 5, 8-10 and 20.

Claims 1-6, 8-12 and 20 were rejected under 35 U.S.C. 102(b) as being anticipated by Healy et al. (US Pat. No. 5,670,161) ("Healy"). The Examiner stated:

> "Healy disclose an expandable, biodegradable stent for use within a body lumen comprising a hollow tube made from a copolymer of L-lactide and caprolactone, wherein the stent incorporates surface coatings or thin films having a thickness of about 25 microns and whereby suitable polymers include polyethylene glycol, polyvinyl alcohol, polyvinyl pyrrolidone, polymethacrylic acid and polyacrylamide that are blended and copolymerized with biodegradable materials. The film may coat only surfaces of the stent or may extend over the micro-machined perforations in the stent. The stent may also desirably incorporate one or more drugs, growth factors and inhibitors (see reference column 5, lines 27-60); (col. 10, lines 10-48); and claims."
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> (Office Action mailed 6/30/2003, pp. 3:20-24 to 4:3-4).

As previously described, claim 1 has been amended without prejudice to recite, *inter alia*, implant for compensating for pathological changes in the spinal column, wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo. Healy does not disclose, teach, or suggest an implant "wherein the varnish-like biodegradable polymer covers a body having substantially constant physiochemical state under physiological conditions in vivo." Rather, as acknowledged by the Examiner, Healy discloses an expandable and biodegradable stent. The biodegradable stent of Healy, therefore, does not have substantially constant physiochemical state under physiological conditions in vivo as required by claim 1. Hence, applicant's respectfully submit that Healy does not disclose, teach, or suggest each and every limitation of claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) has been over come and should be withdrawn.

With respect to claims 2-6, 8-12 and 20, which depend from independent claim 1, applicants submit that because these claims define more particular aspects of applicants' invention in addition to the features and elements of independent claim 1, these claims are also patentably distinct from Healy for the same reasons as claim 1, as well as the additional features of claims 2-6, 8-12 and 20.

Claims 13-15, 18, 19 and 24-28, which depend from claim 1, were rejected under 35 U.S.C. 103(a) as obvious over Arm. Applicants submit that because these claims define more particular aspects of applicants' invention in addition to the features of independent claim 1, these claims are also patentably distinct from Arm for the same reasons

as claim 1, as well as the additional features of claims 13-15, 18, 19 and 24-28. Moreover, Arm is understood to teach way from the limitations of 13-15, 18, 19 and 24-28 for the reasons previously described with respect to claims 1 and 21. Accordingly, applicants respectfully submit that the rejection of claims 13-15,18, 19 and 24-28 under 35 U.S.C. § 103(a) as obvious over Arm has been overcome and should be withdrawn.

New independent claim 32 and dependent claims 33-56 recite features of an orthopedic implant having a fixed contour comprising a metallic body defining a periphery, the periphery generally corresponding with the fixed contour of the implant, and an abrasion-resistant, biodegradable polymer deposition on the periphery. Claim 32 defines over Arm, Eitenmuller, and Healy, for example, by reciting that the implant has a metallic body and an abrasion-resistant, biodegradable polymer deposition. Claim 39 further requires that the polymer deposition comprises a substantially amorphous polymer structure.

New independent claim 57 and dependent claim 58 also recites features of an orthopedic implant having a fixed contour. Claims 57 and 58 define over Arm, Eitenmuller, and Healy, for example, by reciting the implant comprises a body defining a periphery, the periphery generally corresponding with the fixed contour of the implant, and an abrasion-resistant, biodegradable polymer deposition on the body.

New independent claim 59 also recites features of an orthopedic implant and defines over Arm, Eitenmuller, and Healy, for example, by reciting the implant comprises a member, and an abrasion-resistant, biodegradable polymer deposition on the member, wherein at least a portion of the polymer deposition is adapted to promote osteosynthesis.

In view of the foregoing amendments and remarks, it is submitted that all rejections have been overcome and should be withdrawn, and all claims are in condition for allowance. Reconsideration of the application in view of the foregoing amendments and remarks is respectfully requested. The Examiner is invited to call the undersigned if a telephone call could help resolve any remaining items.

Applicants believe that fees are due in connection with the submission of this amendment as calculated on the attached Fee Transmittal Sheet. In this regard, applicants note they have previously paid for three independent claims but only one of the two original independent claims are pending. Accordingly, as calculated on the attached Fee Transmittal Sheet applicants have estimated the required fee based on one extra independent claim.

Should any other fees be required, however, please charge all required fees under 37 C.F.R. 1.17 to Pennie & Edmonds Deposit Account No. 16-1150.

Respectfully submitted,

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